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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,635	03/02/2004	Joseph Rock	US010382A	3051

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
PATEL, NATASHA	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,635	ROCK ET AL.	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 Mar. 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Benhalima et al. (US Patent 6,142,941).

3. Regarding Claim 1, Benhalima discloses a disposable sheath (see covering of cable 14); a conductor integrated in the sheath (see wire inside cable 14); and a transthoracic pad (see external self-adhesive electrode 13) connected to the sheath (see Figure 4) and that includes providing the cardiac stimulation to the patient in combination with the conductor (see col. 4, lines 15-20) by providing two conductive paths, wherein the transthoracic pad acts as a cathode in a first conductive path that travels from the conductor to the transthoracic pad via a chest wall of a patient and as an anode in a second conductive path that travels from the transthoracic pad to the conductor via the chest wall. The examiner considers that cable 14 is covered with some type of insulative material because a cable is defined as "a bound or sheathed group of mutually insulated conductors" (*The American Heritage® Dictionary of the English Language, Fourth EditionCopyright © 2000*). Furthermore, the examiner considers that anything is inherently disposable. Finally, the examiner considers that the

transthoracic pad is *capable* of providing stimulation via either conductive path depending on the needs of the system [emphasis added].

4. Regarding Claim 2, Benhalima further discloses an electrically conductive, insulated cable (cable 14) embedded in the sheath (see covering of cable 14) and extending from the conductor to a proximal end of the sheath to the transthoracic pad (electrode 13), and a connector receiving the cable and connecting the sheath and the transthoracic pad to a defibrillator (see col. 4, lines 19-21) for the cardiac stimulation. The examiner considers that cable 14 is an insulated cable because it is embedded in the sheath and that it is electrically conductive because of the wire that runs thorough this sheath. Furthermore, the cable inherently extends from the conductor (wire inside cable 14) to the proximal end of the sheath before it connects to the transthoracic pad because the cable comprises the conductor and the proximal end of the sheath. Finally, in Figure 4, it is visible, although unlabelled, that there exists some structure (connector) for connecting cable 4, and consequently the transthoracic pad, to the defibrillator.

5. Regarding Claim 3, Benhalima discloses that the conductor is located at or near a distal end of the sheath (see col. 4, lines 15-21). The examiner considers that since the conductor runs along the entire length of the sheath, it necessarily is located at the distal end of the sheath as well.

6. Regarding Claim 4, the examiner considers that the sheath naturally comprises a flexible membrane material because most cable coverings are able to bend and move easily (see Figure 4). Additionally, the fact that the cable covering covers the wires inside make the cable covering a membrane material, inherently.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 5, 7-9, 11, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benhalima et al. (US Patent 6,142,941).

9. Regarding Claims 5 and 15, Benhalima discloses a probe insertable through a mouth into an esophagus of a patient (see endoscope 1), wherein the probe is covered by a sheath (see covering of cable 9), and wherein the sheath comprises an insulation type coating comprising suitable dielectric strength inside a cavity of the sheath to protect the probe from damage by energy applied during the cardiac stimulation. Although the sheath of cable 9 is separate from the sheath of cable 14, it would have been obvious to one having ordinary skill in the art at the time of the invention to put the components of cable 9 and the components of cable 14 in the same sheath, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (*Nerwin v. Erlichman,* 168 USPQ 177, 179). Finally, the purpose of insulation is to separate the conductor (cables 9 and 14) from conducting bodies (probe 1 and electrode 13) by means of nonconductors (the sheaths) so as to prevent transfer of electricity, heat, or sound (*Merriam-Webster's Medical Dictionary, © 2002 Merriam-Webster, Inc).* Thus, the insulative sheaths of cables 9 and 14 inherently

have a suitable dielectric strength to protect the probe from damage during stimulation; otherwise, the insulative sheaths would not be insulative.

10. Regarding Claim 7, see rejections of similarly worded Claims 1 and 5 above. As to a disposable sheath slidably covering the probe, the examiner considers that the insulative covering of cable 9 is *capable* of being slid since the insulative covering is simply a membrane and is not fused, or fixedly attached, to the conductive wires inside of cable 9).

11. Regarding Claim 8, see rejection of similarly worded Claim 2 above.

12. Regarding Claim 9, see rejection of similarly worded Claim 3 above.

13. Regarding Claim 11, see rejection of similarly worded Claim 4 above.

14. Regarding Claim 16, Benhalima discloses that the transthoracic pad is positioned over the thorax of the patient (see col. 4, lines 15-17). The examiner considers that the sternum is part of the thorax and thus, electrode 13 is positioned over the thorax.

15. Claims 6, 12-14, 17-18, and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benhalima et al. (US Patent 6,142,941) in view of Pless et al. (US Patent 4,640,298).

16. Regarding Claims 6 and 17, Benahlima does not disclose an inflatable balloon. However, Pless discloses a similar esophageal probe that has an insulating sheath (see sheath 3; col. 5, line 43) further comprising an inflatable balloon (see either balloon 4Y or 4Z) positioned behind the conductor (see electrode material 5 in Figure 2) closing a gap between the esophagus and the sheath and pushing the conductor against a wall of the esophagus (see col. 4, lines 59-63). It would have been obvious to one of ordinary

skill in the art at the time of the invention to incorporate Pless's inflatable balloon configuration in order to achieve the desired close contact between electrodes and the heart, thereby reducing current intensity and potential differences as taught by Pless (see col. 3, lines 12-16).

17. Regarding Claims 12-14 and 21-23, Benhalima does not elaborate upon which chambers of the heart are to be defibrillated or paced. Pless, however, discloses stimulation zones that include the atria and the ventricles (see col. 7, line 53-col. 8, line 12). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide an esophageal probe that stimulates any of a plurality of sites within any of the chambers of the heart because Pless teaches that it provides the greatest flexibility in the application of the probe (see col. 7, lines 55-57).

18. Regarding Claim 18, see rejections of similarly worded Claims 1, 3, and 6 above. Furthermore, the examiner considers that one conductive path would have to be selected initially for use because both conductive paths could not be selected for use at the same time. There would be no transmission of signals to the conductor if the transthoracic pad were both an anode and a cathode. Since, the transfer of pulses from the defibrillator to the transthoracic pad is critical to Benhalima's invention, it is necessary that the transthoracic pad be only a cathode or only an anode at a given time.

19. Regarding Claim 20, see rejection of similarly worded Claim 4 above.

20. Regarding Claim 24, see rejection of similarly worded Claims 5, 7, and 18 above.

21. Regarding Claim 25, see rejection of similarly worded Claim 5 above.

22. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benhalima et al. (US Patent 6,142,941) in view of Crowley (US Patent 5,588,432).

23. Regarding Claim 10, Benhalima discloses an ultrasonic transducer at the end of the probe for performing the trans-esophageal echocardiography (see col. 2, lines 19-22). However, Benhalima does not disclose that the conductor is acoustically transparent. Crowley teaches catheter construction using acoustically transparent conductors for the purpose of enabling sensing and stimulation of tissue while not obstructing the monitoring of the tissues acoustically. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acoustically transparent conductors in the modified Benhalima system in order to avoid compromised acoustically monitoring results that fail to disclose the impact of the acoustical testing on all the tissue in the test site (see col. 14, lines 31-36).

24. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benhalima et al. (US Patent 6,142,941) in view of Pless et al. (US Patent 4,640,298), and further in view of Crowley (US Patent 5,588,432).

25. Regarding Claim 19, see rejection of similarly worded Claim 10 above.

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
8/18/06

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766